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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,103	03/06/2001	Gregory Donoho	LEX-0143-USA	2742

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LEXICON GENETICS INCORPORATED
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EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 03/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/800,103

Applicant(s)

DONOHU ET AL.

Examiner

Robert Landsman

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 13 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Formal Matters

- A. Amendment B, filed 1/14/03, has been entered into the record.
- B. Claims 1-3, 13 and 14 are pending and are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.
- D. The Examiner appreciates Applicants' submission of a clean copy of all pending claims.

2. Title

- A. The objection to the title has been withdrawn in view of Applicants' amendment.

3. Abstract

- A. The objection to the Abstract has been withdrawn in view of Applicants' amendments.

4. Claim Rejections - 35 USC § 101

- A. Claims 1-3, 13 and 14 remain rejected under 35 USC 101 for the reasons already of record on pages 3-6 of the Office Action dated 9/10/02. Applicants argue that the presently claimed protein is clearly referred to as a transporter protein and that these proteins transport material across the lipid bilayer. Applicants argue that this situation is not analogous to *Brenner v. Manson* and that the function of transporters is well known. Applicants also argue that the references cited by the Examiner, on a whole, support the assertion that a protein's function can be (or is at least more likely than not) predicted based on homology and that, in the present situation, the function of transporter proteins are well-known.

These arguments have been considered, but are not deemed persuasive. Though Applicants' have clearly stated that the protein of the present invention is a transporter protein and that homology, at times, may be used to predict the function of a protein, Applicants have still not provided any conclusive evidence that the protein of the present invention is a transport protein. Contrary to Applicants' arguments, the Examiner is not implying that a real-world utility does not require further characterization, only that a patent is not a "hunting license." If Applicants were able to establish that the protein encoded for by the polynucleotide of the present invention was a transporter protein, then further characterization would be acceptable.

The use of the polynucleotide of the present invention in such applications as the Human Genome Project does not confer a specific use for the polynucleotide of the present invention, or its encoded protein. In other words, though the Human Genome Project itself may be substantial and credible, it does not provide a substantial or specific utility of the polynucleotide of the present invention. Similarly, the argument that the claimed polynucleotide sequences can be used to track the expression of the genes encoding the described proteins, or that uses such as "for DNA chips," "chromosomal mapping," or other "markers" is not persuasive since these uses, again, are neither specific or substantial since any nucleotide sequence can be used in such an assay. While it is clear that the nucleic acid molecule of the present invention would hybridize to a chromosome, without knowing the function of the protein encoded for by this nucleic acid molecule, then simply identifying that a nucleic acid molecule localizes to a particular region of a chromosome would not provide a use for the nucleic acid molecule of the present invention. Finally, Applicants argue that the USPTO has issued numerous patents which appear to contain proteins with no identifiable functions. However, all issued patents are presumed to have a utility.

5. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

A. Claims 1-3, 13 and 14 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on page 6 of the Office Action dated 9/10/02 as well as for the reasons given in the above rejection under 35 USC 101. Applicants argue that the claimed invention is enabled because it has utility as argued previously. Applicants' arguments have been fully considered, but are not found to be persuasive for the reasons discussed above.

B. The potential rejection of claims 1, 13 and 14 under 35 USC 112, first paragraph, regarding "at least 24 contiguous bases" has been withdrawn in view of Applicants' amendment to the claim to cancel this limitation.

6. Claim Rejections - 35 USC § 112, first paragraph – written description

A. The rejection of claim 1 under 35 USC 112, first paragraph, regarding "at least 24 contiguous bases" has been withdrawn in view of Applicants' amendment to the claim to cancel this limitation.

7. Claim Rejections - 35 USC § 112, second paragraph

A. The rejection of claim 2 under 35 USC 112, second paragraph, regarding "hybridization conditions" has been withdrawn in view of Applicants' amendment to the claim to recite the specific hybridization conditions.

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8. Claim Rejections - 35 USC § 102

A. The rejection of claim 1 under 35 USC 102(b) as being anticipated by Hillier et al. regarding "at least 24 contiguous bases" has been withdrawn in view of Applicants' amendment to the claim to cancel this limitation.

9. Conclusion

A. No claim is allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory information


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
February 25, 2003


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600